

REMARKS

Claims 1-3 and 8 have been amended. Claims 1-8, 10, 48, and 57-58 are pending in the instant application. The amendments to the claims merely serve to clarify the nature of the claims or are fully supported by the specification, for example on page 27, lines 20-24, on page 26, lines 19-23, on page 30, lines 7-10, and on page 17, lines 11-22. Thus the amendments do not constitute new matter.

The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Claim Objections

The Office Action has objected to Claims 8 and 10 under the assertion that they are in improper form. Applicants respectfully traverse this assertion, but have amended Claim 8 to clarify the nature of the claim. Applicants contend that Claim 8 as amended, and Claim 10, dependent on amended Claim 8, are in proper form. Applicants further contend that the amendments to Claim 8 in no way limit or alter the scope of the claims. Applicants therefore request reconsideration and withdraw of the objection to Claims 8 and 10.

2. Claim Rejections Under 35 U.S.C. §101

The Office Action maintains a rejection of claims 1-8, 10, 48, and 57-58 under 35 U.S.C. § 101 as not supported by a substantial or well-established utility. Applicants respectfully traverse this assertion.

Applicants contend that contrary to the assertion of the Office Action, the specification does in fact set forth a substantial utility for the claimed invention that would be credible to one of ordinary skill in the art. The specification teaches nucleic acid molecules encoding novel human proteins (Figures 1-4). The specification also teaches homologous murine sequences (Figures 5-7). The specification teaches that such nucleic acid molecules can be used to map gene locations and those of related genes (page 122, lines 11-15), to develop antisense probes (page 122, line 23 *et seq.*), and in gene therapy to create a dominant-negative inhibitor (page 123, lines 10-18). The specification further teaches that the encoded polypeptides may be used therapeutically in

combination with other factors as appropriate (page 122, lines 19-21), and as an immunogen, where the corresponding antibodies may be used to prevent, treat, or diagnose a number of diseases or disorders (page 123, line 19 *et seq.*).

Additionally, the specification teaches that the murine ortholog protein shows a specific phenotype in transgenic mice – *i.e.* it induces seminal vesicle hyperplasia (page 93, lines 7-12). Applicants contend that contrary to the assertion of the office, one of ordinary skill in the art would recognize and find credible the nexus between the murine ortholog sequence and the polypeptide sequences set forth in SEQ ID NO: 2, 4, or 6 (or the nucleic acid molecules set forth in SEQ ID NO: 1, 3, or 5). Applicants present in Exhibit A sequence alignments of SEQ ID NO: 14 individually with SEQ ID NO: 2, 4, and 6. Applicants note that SEQ ID NO: 2 shares a 61.1% identity in 108 amino acids, and a 53.3% identity in 92 amino acids with SEQ ID NO: 14. SEQ ID NO: 4 shares a 61.0% identity in 105 amino acids, and a 53.3% identity in 92 amino acids with SEQ ID NO: 14. And SEQ ID NO: 6 shares a 57.9% identity in 114 amino acids, and a 53.3% identity in 92 amino acids with SEQ ID NO: 14. Summarizing, SEQ ID NO: 2, 4, and 6 share substantial identity in at least two major regions with SEQ ID NO: 14. Thus one of ordinary skill in the art would recognize that the polypeptides set forth in SEQ ID NO: 2, 4, or 6 could be used, for example, to develop agonists or antagonists useful in the treatment of reproductive disorders and proliferative disorders. Accordingly, Applicants contend that one or ordinary skill in the art would recognize that the claimed molecules have credible, specific, and substantial utility.

Applicants respectfully submit that because the instant application contains an assertion of a substantial utility for the claimed invention, the rejection under 35 U.S.C. § 101 should be withdrawn.

3. Claim Rejections Under 35 U.S.C. §112, first paragraph

(A) The Office Action maintains a rejection of claims 1-8, 10, 48, and 57-58 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in such a way as to enable one of skill in the art to which it pertains, or with which it is most clearly connected, to make and use the invention. The Office Action states that because the claimed invention is not supported

by either a well asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Applicants contend that this ground of rejection stands or falls with the rejection asserted in the Office Action under 35 U.S.C. § 101. As set forth above, applicants have provided affirmative evidence that the asserted utility would be credible to one of ordinary skill in the art. Applicants respectfully contend that because the instant application in fact contains an assertion of a specific and substantial utility for the claimed invention that one of ordinary skill in the art would find to be credible, this rejection under 35 U.S.C. §112, first paragraph, is overcome, and should be withdrawn.

(B) The Office Action asserts a rejection of Claims 1-8, 10, 48, and 57-58 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that “a nucleotide sequence that hybridizes to the complement of the nucleotide sequence of either (a) or (b) at 65°C in a hybridization buffer comprising 0.015M sodium chloride and 0.0015M sodium citrate” is not supported by the specification as filed. Applicants respectfully traverse this assertion.

The specification, on page 27, lines 20-24, provides hybridization conditions such that one of ordinary skill in the art would recognize that the Applicants were in possession of the invention as claimed. Nevertheless, solely in order to expedite prosecution, Applicants have amended Claims 1-3 to reflect more specifically the disclosure of the specification. Support for the amendments may be found on page 27, lines 20-24. Applicants contend that as amended, Claims 1-3, and dependent claims 4-8, 10, 48, and 57-58 comply with the written description requirement of 35 U.S.C. §112, first paragraph.

Applicants, believing that the rejection of the pending claims based on 35 U.S.C. §112, first paragraph, have been overcome by amendment or traversed by argument, respectfully request that this ground of rejection be withdrawn.

4. Claim Rejections Under 35 U.S.C. §102

The Office Action asserts a rejection of Claims 1-3 under 35 U.S.C. 102(b) as anticipated by Hillier *et al.* (GenBank Accession No. N47851). Specifically, the Office Action asserts that this reference anticipates Claims 1-3 because it teaches a nucleotide sequence that hybridizes to the

complement of the nucleotide sequence of any of SEQ ID NO: 1, 3, or 5 under the recited hybridization conditions, referring to nucleotides 73-172 of N47851. Applicants respectfully traverse this assertion.

Applicants first note that Claims 1-3 have been amended, incorporating % identity language into section (c) of each of these claims. Support for these amendments may be found on page 26, lines 19-23, on page 30, lines 7-10, and on page 17, lines 11-22. Applicants contend that Claims 1-3, as amended, are not anticipated by Hillier *et al*. With regard to Claim 1, the claim has been amended such that any hybridizing sequence of section (c) must be “at least 75% identical to the nucleotide sequence of either (a) or (b).” As the sequence of Hillier is not at least 75% identical to the nucleotide sequence of either (a) or (b), it does not anticipate Claim 1 as amended. Claims 2-3 have been similarly amended, and additionally amended such that the nucleotide sequences of (a) and (b) are at least 150 nucleotides in length. Thus the sequence of Hillier does not anticipate Claims 2-3 as amended.

Accordingly, Applicants, believing that the rejection of the pending claims based on 35 U.S.C. §102, have been overcome by amendment or traversed by argument, respectfully request that this ground of rejection be withdrawn.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Whiteman believes it to be helpful, he is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Dated: January 26, 2005

By: Sherri L. Oslick
Sherri L. Oslick, Ph.D.
Reg. No. 52,087